COSMETIC MASK COMPOSITION

Field of the invention

The present invention relates to a cosmetic composition, particularly a self-curing mask, to be used as an "anti-ageing" treatment.

Background of the art

Cutaneous ageing is a widely studied phenomenon and constitutes a particularly felt problem throughout the population, particularly female, both in relation to age and to the ever more frequent exposure to solar rays. Photo-induced cutaneous ageing is caused by the fact that ultraviolet rays induce errors in the transcription of some epithelial cell genes, which are thus not able to carry out all their normal functions. In practice, senescent keratinocyte cells stop growing and do not enter into the cell cycle S-phase, independently of any mitotic stimulation, and some genes required for the cell cycle are inhibited. However, the senescent keratinocytes maintain normal metabolic activity as well as the possibility of synthesising protein or RNA for a certain period of time.

Retinoic acid, or tretinoine, is a known molecule used for a very long time for the treatment of cutaneous ageing, acne and Dischromia. Its properties make it extremely

efficacious and unique within its kind. Indeed, it has the capacity to regularise sebaceous secretions, thin the corneous layer, thicken the epidermis, organise the distribution of melanin and, above all, by acting through specific receptors, succeeds in reaching the cell nucleus and modulating gene transcription; it is the latter which is its most important characteristic in the therapy of photo-induced cutaneous ageing.

The constant application of retinoic acid to the skin may however result in the onset of an adverse reaction defined in the literature as "retinoid dermatitis" which manifests itself through reddening, burning, itching, exfoliation and also palpebral oedema.

For this reason, tretinoine is used medicinally in the form of creams or lotions, at low concentrations. This means *i.e.* creams of 0.025-0.05 % up to lotions reaching 1% by weight. The use of higher amounts of retinoic acid, up to 5% by weight, has been tried in a lotion with encouraging results with reference to "anti-ageing" activity, but with the adverse result that some treatments had to be interrupted due to the onset of significant irritative phenomena.

Summary of the invention

The problem which lies at the heart of the present invention is that of providing a retinoic acid based cosmetic composition, which may fulfil its anti-ageing activity without giving rise to side effects such as the irritative effects of the epidermis.

Such problem is resolved by a cosmetic composition in the form of a mask containing retinoic acid together with cosmetically acceptable excipients, wherein said retinoic acid is comprised in amounts up to 20% by weight with respect to said cosmetic excipients, such as depicted in the enclosed claims.

Preferably, the amount of retinoic acid will be comprised of between 1% and 18% by weight, with respect to the weight of said cosmetic excipients.

More preferably, the amount of retinoic acid will be comprised of between 4% and 16% by weight, still more preferably, it will be greater than 5% and up to 15% by weight, with respect to the weight of the cosmetic excipients.

By the term "retinoic acid" in the present description is meant trans-retinoic acid (natural isomer, all-trans retinoic acid), the various *cis* isomers of retinoic acid, 3,4-didehydroretinoic acid, or mixtures thereof.

The mask of the invention will preferably be a self-curing mask.

Detailed description of the invention

The mask of the invention comprises an amount by weight of retinoic acid, calculated according to the weight of the cosmetic excipients, of up to 20%, preferably between 1% and 18%, more preferably between 4% and 16%, still more preferably, greater than 5% and up to 15%.

The mask of the invention allows using high concentrations of active ingredient without having any adverse irritative reactions, and hence significantly reducing the clinical result attainment times. The mask, by virtue of its "occlusive pharmaceutical form" nature, by increasing the bioavailability of the active ingredient, allows the attainment of maximum penetration of retinoic acid, significantly reducing the number of applications and their frequency. For example, if the low concentration cream must be applied twice daily continuously for 3-4 months, conversely the mask may be applied every 7-14 days for 3-5 times. The clinical results are much more evident and the side effects are absent.

Indeed, creams and lotions remain on the cuteous even after treatment, whilst the removal of the self-curing mask

allows the reduction of the contact time of the retinoic acid with the skin. The increased bioavailability of the retinoic acid administered in this form allows its rapid penetration as far as reaching the target cells.

Furthermore, the occlusive form traps water within the skin thus inhibiting cutaneous transpiration: water performs an anti-inflammatory action.

This all makes the incidence of the occurrence of retinoid reactions practically insignificant, and hence allows the attainment of the clinical result in rapid times and without any discomfort for the patient.

The mask of the invention can be a facial mask or a mask for neck or hands, or a mask for any part of the body, as the need may be.

The mask of the invention comprises retinoic acid together with cosmetically acceptable excipients. Such excipients will be selected from those normally used for the preparation of masks, particularly for the preparation of self-curing masks.

The amounts of the individual cosmetically acceptable excipients reported throughout the description are

calculated depending on the total weight of the excipients in the composition.

Particularly, the composition of the invention will contain a hydrophilic polymer intended to form the load bearing structure of the mask. Such hydrophilic polymer will preferably be selected from vinyl polymers with hydrophilic characteristics. More preferably, the hydrophilic polymer will be polyvinyl alcohol. Such hydrophilic polymer may be used in amounts by weight generally comprised of between 5% and 22%, preferably between 8% and 18%, more preferably between 9% and 13%, calculated based on the total weight of the excipients.

The mask may further contain ethyl alcohol, normally 95° ethyl alcohol, or other alcohol or cosmetically acceptable solvent, functioning as a mask curing time modulating agent. Generally, by increasing the concentration of ethyl alcohol, a reduction in curing time is obtained, and *vice versa*. Normally, amounts by weight of ethyl alcohol comprised of between 10% and 20% with respect to the total weight of the excipients will be used. With an ethyl alcohol amount of around 15%, mask curing times in the order of 35-40 minutes will be obtained. Longer curing times will be obtained with ethyl alcohol amounts of around 10% by weight. Choice of the curing

time will be made in the light of particular clinical exigencies. Indeed, the curing time of the mask also determines the time the formulation spends in contact with the skin, in that only the cured mask may be removed.

The mask of the invention may furthermore contain gelifying agents. The gelifying agents normally used will be selected from acrylic polymers with molecular weight preferably comprised of between 940 and 2001. Preferred acrylic polymers will be high dispersability acrylic polymers, such as the ETD class acrylic polymers. Said acrylic polymers will preferably be used in amounts by weight comprised of between 0.1% and 1.5%, more preferably between 0.2% and 1%, still more preferably between 0.3% and 0.7%. Other usable gelifying agents are celluloses, preferably hydroxyethylcellulose. The celluloses are usable in amounts preferably comprised of between 0.1% and 1%, more preferably between 0.3% and 0.7%. Other usable gelifying agents are selected from among the gums, such as tragacanth gum or xanthan gum, more preferably the latter. The amounts of gum used will preferably vary between 0.1% and 1%, more preferably between 0.3% and 0.7%.

The use of gelifying agents in lesser or greater amounts has the aim of giving the composition a lesser or greater consistency. The use of acrylic polymers is

generally preferred to that of celluloses, in that the latter tend to adhere better to the cuteous, thus being able to perform, during the removal of the mask, a depilating effect.

The mask of the invention may furthermore contain pH regulators, particularly acidity regulators. Such additives will preferably be alkaline substances, such as cosmetically acceptable organic or inorganic bases. An example of an organic base is triethanolamine. The organic bases will preferably be used in amounts comprised of between 0.1% and 0.6 %, more preferably between 0.2% and 0.4%. An example of an inorganic base is sodium hydroxide in dilute solution, preferably a 1N solution. The inorganic bases will preferably be used in concentrations comprised of between 0.1% and 0.2%.

The mask of the invention may furthermore contain a humectant agent. Such humectant agent will preferably be a polyol, preferably a triol or a glycol. Particularly preferred humectant agents will be glycerine and/or propylene glycol. Preferred amounts of humectant agent will vary between 1% and 20%, preferably between 2% and 17%, more preferably between 4% and 10%, still more preferably between 5% and 8%. Said humectant agents may also be used in mixtures. Particularly, a glycol,

preferably propylene glycol, may be used in order to solubilise the retinoic acid during the preparation of the cosmetic composition of the invention, as will be better described in the following.

The mask of the invention may also contain chelating agents or sequestrants. A specific example of a chelating agent is ethylenediaminetetraacetic acid (EDTA). The amount of chelating agent used in the composition of the invention will preferably vary between 0.01% and 0.2%, more preferably between 0.05% and 0.15%.

The mask of the invention may furthermore contain cosmetically acceptable non-ionic surfactants, such as for example PEG 7 glyceryl cocoate, PEG 6 triglyceryl caproic glycerides, polyquaternum 7. Such surfactants, taken individually or in mixture, will preferably be used in variable amounts between 0.5% and 6%, more preferably between 1.5% and 4.5%.

The mask of the invention may furthermore comprise preservatives, preferably in amounts comprised of between 0.1% and 1.5%, more preferably between 0.2% and 1%. Usable preservatives are for example selected from among methyl parabenes and/or imidazolidinyl urea, singularly or in mixtures thereof.

The cosmetic composition of the invention will finally comprise water, in sufficient amount in order to adjust the composition of the excipients to 100%, with a diluent/solubilising function.

According to a particularly preferred form of the mask of the present invention, the cosmetic composition is made particularly "soft" through the addition of a cream base of the type normally used for the face, the hands or the body. The amount of cream base will preferably vary between 0.2% and 1%, more preferably between 0.4% and 0.7%, still more preferably around 5%, with respect to the weight of the excipients. According to the needs dictated by the typology of the patients skin, it will be possible to use a cream base for normal skin types, for greasy skin types and for mixed skin types.

The composition of such cream base will not differ from the standard creams normally used for such purposes and may however comprise (% by weight calculated based on the total weight of the cream):

- a lipid component, preferably between 2% and 8%;
- an emollient, preferably between 0.5% and 15%;
- a humectant agent, between 0% and 2%;
- a gelifying agent, between 0% and 1%;
- a surfactant, between 1% and 10%;

- a preservative, between 0.3% and 1%;
- collagen, between 0% and 20%;
- a pH regulator, sufficient to correct the pH to physiological values;
- water, sufficient to adjust the composition of the cream to 100%.

Generally, a higher percentage of lipid component will be indicated in the case of cream for greasy skin types.

High percentages of emollient will be indicated for normal skin types, whilst lower amounts will be used on greasy skin types.

The use of collagen will be particularly indicated for normal skin types.

The cosmetic excipients used in the cream will be generally but not limitingly selected from among those listed previously in the various categories of substances and will be generally selected from among those normally used in analogous cosmetic preparations, well known to any expert in the art.

By way of example, a description will now be provided of the general preparation method of the cosmetic

composition of the invention and some examples of specific compositions which may be used as self-curing masks.

PREPARATION OF THE COSMETIC COMPOSITION

The preparation of the cosmetic composition in the form of a mask according to the invention provides a first operative stage (Stage I), wherein a stock composition of the excipients is obtained, and a subsequent operative stage (Stage II) wherein said stock composition is combined with a solution of retinoic acid. The first stage is in turn divided into two steps A and B.

STAGE I

Step A

The chelating agent and/or sequestrant and the gelifying agent are added to the predetermined amount of water. This is allowed to stand for around 2 hours, after which it is neutralised with an acidity regulator and the surfactant is added. In the case of various surfactants, these may be added sequentially or pre-mixed.

Step B

The hydrophilic polymer and the humectant agent are heated to around 80°C and the resulting mixture is combined

with the mixture obtained in step A, itself also heated to around 80°C.

The mixture resulting from the combining of the products of steps A and B is cooled to around 35°C and the preservative agent and the mask curing time modulating agent, normally ethyl alcohol, are added.

STAGE II

The desired amount of retinoic acid, in the proportions previously indicated, determined according to the clinical needs of the patient, are added to the solvent, preferably propylene glycol, which has been previously heated to around 40°C, after which the resulting solution is blended by turbo-emulsification into the stock composition of Stage I.

The amount of solvent (propylene glycol) used in order to solubilise the retinoic acid generally varies from 0.5% to 10% by weight with respect to the total weight of the excipients.

As mentioned previously, the mask may be made even softer through the addition, in the prior indicated proportions, of a cream base, prepared according to the

normal methods well known to any expert in the art, by starting from the raw materials listed above.

EXAMPLE 1 - Preparation of a cosmetic composition for a self-curing mask

The method described above for the preparation of 100 g of stock composition of excipients is followed. The stock composition of excipients has the following percentage composition (by weight):

Carbopol 940 ETD	0.5
Triethanolamine	0.3
Purified water	63.4
Glycerine	6
Imidazolidinyl urea	0.3
EDTA	0,1
Polyvinyl alcohol	10
Methyl parabenes phenoxyethanol	0,5
95° ethyl alcohol	14.9
Peg 7 glyceryl cocoate	1.5

Peg 6 Triglyceryl Caproic Glycerides 1.5

Polyquaternum 7 1

15 g of retinoic acid is dissolved in 10 g of propylene glycol at 80°C and such solution is added, according to the method previously set out, to the stock composition of excipients.

The resulting composition is inserted into 20 ml capacity aluminium tubes for storage.

EXAMPLE 2

The preparation of example 1 is repeated, using an amount of retinoic acid of 10 g.

0.5 g of a cream for normal skin types, as defined below, is added to the cosmetic composition.

EXAMPLE 3

The preparation of example 1 is repeated, using an amount of retinoic acid of 5 g.

0.5 g of a cream for greasy skin types, as defined below, is added to the cosmetic composition.

EXAMPLE 4

The preparation of example 2 is repeated, but the cream base for normal skin types is substituted with a cream base for mixed skin types.

PREPARATION 1 - Cream base for normal skin types

2000 g of cream base is obtained according to the normal methods used for the preparation of cosmetic cream, by starting from the following raw materials:

Acemulgor LAM V	160 g
Isopropylmyristate	60 g
Tegosoft CT	80 g
Cetylstearyl alcohol	60 g
Glycerine	20 g
Xanthan gum	6 g
Purified water	1240 g
Abil B 8839	60 g
Sepicide Hb	8 g
Collagen Hyal	300 g
Sepicide CI	6 g

Lactic acid	100 drops

PREPARATION 2 - Cream base for greasy skin types

1,000 g of cream base is obtained according to the normal methods used for the preparation of cosmetic cream, by starting from the following raw materials:

PLANTA CREAM V 40	100 g
ACEMOL OCT	60 g
ISOFOL 20	40 g
TEGOSOFT CT	40 g
ABIL 350	10 g
WATER	740 g
PROPYLENE GLYCOL	5 g
SEPICIDE CI	2 g
SEPICIDE HB	3 g

PREPARATION 3 - Cream base for mixed skin types

2000 g of cream base is obtained according to the normal methods used for the preparation of cosmetic cream, by starting from the following raw materials:

ACEMULGOR EC	130 g
ACEMOL OCT	70 g
ACEMOL L	60 g
LIGHT VASELINE OIL	40 g
WATER	1450 g
GLYCERINE	20 g
WATER	200 g
SEPICIDE CI	6 g
SEPICIDE HB	4 g
CETYLSTEARYL ALCOHOL	20 g

MASK APPLICATION METHOD

Application of the mask must be carried out by skilled medical staff and in a suitable environment.

The preparation has the appearance of a dense yellow paste which must be spread homogeneously over the body part of the patient to be treated, for example the patient's face, covering all the areas affected by signs of ageing from solar rays and paying close attention to the most

sensitive areas, such as the areas closest to the eyes and mouth.

The mask of example 1 cures over a period of approx. 30 minutes, following which it is easily removed by an action known as "tearing off".

The treatment may be repeated every 7-14 days for a number of sessions which varies depending on the skin requiring treatment. Normally the number of sessions will be from 3 to 5.

Absolute contraindications to the treatment are constituted by a known allergy towards retinoic acid and pregnancy.

The skin treatment method of a patient subject to signs of cutaneous ageing according to the invention allows the attainment of excellent results, superior to those obtained with known methods which make use of small amounts of retinoic acid, with the surprising result of not provoking the typical irritation by retinoids which normally already occur with much lower doses of such active ingredient.